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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,182	03/04/2002	S. Christopher Bauer	126181-1014	5061

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/090,182	<b>Applicant(s)</b> BAUER ET AL.	
	<b>Examiner</b> Robert Landsman	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-34 is/are pending in the application.
- 4a) Of the above claim(s) 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 and 32-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/4/02</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *1. Formal Matters*

- A. The Election dated 1/21/05 has been entered into the record.
- B. Claims 27-34 are pending and were subject to restriction in the Paper mailed 11/4/04. In the Response dated 1/21/05 Applicants elected Group I, claims 27 and 31-34 and further elected SEQ ID NO:15. Since claim 31 does not read on the elected sequence, only claims 27 and 32-34 will be searched in this application. Claims 28-31 are withdrawn as being drawn to non-elected inventions. Applicants argue that it would not be an undue burden to search all the inventions. This argument has been considered, but is not deemed persuasive. First, the Examiner wishes to clarify that the restriction should have been drawn to cultured stem cells, not IL-3 proteins. Regardless, the restriction would be identical. The claims are drawn to stem cells cultured in the presence of distinct interleukins. Each of these IL-3 molecules have a distinct structure (as evidenced by their distinct SEQ ID NOs) and would require a different search in the protein databases. A search of one of the IL-3 molecules would not necessarily overlap a search of any other IL-3 molecule. Therefore, the restriction is deemed proper and is made FINAL.
- C. The Information Disclosure Statement dated 9/19/02 has been entered into the record.

### *2. Specification*

- A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The claim is directed to cultured stem cells.

### *3. Priority*

- A. The first line of the specification should be updated since U.S. application 08/764,114 now U.S. Patent 6,440,407.

#### 4. Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 27 and 32-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 41 and 47-50 of copending Application No. 10/144,322. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present invention claims stem cells cultured in the presence of the IL-3 of SEQ ID NO:15. The application claims stem cells cultured in the presence of SEQ ID NO:1 or 4. However, SEQ ID NO:1, 4 and 15 contain hundreds of potential substitutions which could result in millions of possible mutant IL-3 molecules. Though the SEQ ID NOs are different, it is possible to produce the same IL-3 mutant starting with any of SEQ ID NO:1, 4 or 15. The limitations of the claims in each application are the same. Regardless, it would be expected that the same IL-3 mutant would have the same binding and/or functional characteristics.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

B. Claims 27 and 32-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,479,261; claim 1 of U.S. Patent No. 6,440,407; claim 1 of U.S. Patent No. 6,436,387; claim 1 of U.S. Patent No. 6,413,509; claim 1 of U.S. Patent No. 6,074,639 and claim 1 of U.S. Patent No. 5,997,860. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 27 of the present invention recites stem cells cultured in the presence of the IL-3 mutant of SEQ ID NO:15. All of the patents recite a method of ex-vivo expansion of stem cells using various IL-3 mutants, including that of SEQ ID NO:15. The IL-3 mutants of the inventions contain hundreds of potential substitutions which could result in millions of possible mutant IL-3 molecules. Though the SEQ

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ID NOs in the patents may differ from that of the present invention, it is possible to produce the same IL-3 mutant starting with any of SEQ ID NOs of any patent or instant application. Though the patents recite methods of producing stem cells whereas the application recites the stem cells themselves, it would have been obvious to the artisan at the time of the present invention to have had in their possession stem cells in order to perform the methods of the patents. Without the cells, the artisan would not be able to expand these lines.

Even arguing the IL-3 peptides were distinct (which is on the Applicant to prove) it is not known how the stem cells would differ in the presence of these distinct IL-3 molecules since they are, in fact, still IL-3 molecules.

Due to the substantial number of IL-3 applications submitted by Applicant, they are requested to bring to the Examiner's attention any other applications which may raise the issue of double patenting.

## **5. Conclusion**

A. No claim is allowable.


### ***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 9 AM-6 PM (eastern); alt F 9 AM-6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman  
Primary Examiner  
Art Unit 1647

  
ROBERT S. LANDSMAN, PH.D  
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